REMARKS

Election/Restrictions

Claims 10-16, 18, 19, 21, 27, 28, 30, 31, 33-39 and 56-72 have been withdrawn from consideration as being drawn to a non-elected species of the invention. The Applicant has chosen to maintain the withdrawn claims in the pending application for possible reinstatement upon the allowance of one or more generic base claims.

Specification

The specification has been objected to as failing to provide proper antecedent support for the recitation that the packaging comprises a "common container". As set forth immediately below, the Applicant has amended various claims to remove reference to the term "common". Accordingly, the objection to the specification is deemed moot, and withdrawal of the objection to the specification is respectfully requested.

Claim Rejections – 35 USC § 112

Claims 3, 5-9, 17, 20 and 22-26 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Applicant has amended claims 3, 22 and 24 (and withdrawn claims 30, 57, 66 and 70) to remove reference to the term "common". Accordingly, the rejection of the claims as being indefinite is deemed moot, and withdrawal of the rejection of the claims as being indefinite is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 3, 5-9, 17 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0004660 to Henniges et al. in view of U.S. Patent No. 6,273,916 to Murphy. Claims 5 and 6 were rejected as being unpatentable over the Henniges reference in view of the Murphy reference, and further in view of U.S. Patent Application Publication No. 2001/20185 to Ray. Claims 7-9 were rejected as being unpatentable over the Henniges reference in view of the Murphy reference, and further in view of U.S. Patent No. 5,306,309 to Wagner et al. Claims 22-25 were rejected as being unpatentable over the Henniges reference in view of the Murphy reference, and further in view of U.S. Patent No.

4,523,679 to Paikoff et al. Claim 26 were rejected as being unpatentable over the Henniges reference in view of the Murphy reference, and further in view of U.S. Patent Application Publication No. 2003/0093153 to Banick et al.

Independent claim 3 is directed to a surgical kit for use in a spinal surgery and has been amended to recite spinal implant components comprising an elongate spinal plate member and a number of bone screws, surgical instrumentation comprising a driver including an end portion configured to drivingly engage said bone screws into engagement with vertebral bone, and "packaging comprising a single container, each of said spinal implant components and said instrumentation integrally contained and sealed within said single container to maintain said spinal implant assembly and said instrumentation in a sterilized condition prior to the spinal surgery, the surgical kit being self-contained to include all of the components and instrumentation within said single container that are required to perform a designated spinal stabilization procedure." Support for the amendments to independent claim 3 are found, for example, at paragraph [0016] and Figures 1 and 2 of the published application.

As shown in Figures 1 and 2, the plate 20, the bone screws 22, and the driver 24 are all integrally contained and sealed within a single container 30, with the container 30 optionally positioned within an outer tray 32. Although the container 30 may be provided with a number of recessed compartments 34a-34d, the components of the surgical kit 10 are all integrally contained and sealed within a single container 30 via the upper seal 46. Furthermore, as should be appreciated, the surgical kit 10 includes is self-contained so as to include all of the components and instrumentation (i.e., the plate 20, the bone screws 22, and the driver 24) within the container 30 that are required to perform a designated spinal stabilization procedure.

Referring to the Henniges reference, disclosed therein is a spinal plate 10, bone fasteners 12 and a driver tool 24. However, each of the plate 10, the bone fasteners 12 and the driver tool 24 are clearly not "integrally contained and sealed within [a] single container to maintain said spinal implant assembly and said instrumentation in a sterilized condition prior to the spinal surgery", as recited in independent claim 3. Additionally, the Henniges reference does not discloses a surgical kit that is "self-contained to include all of the components and

instrumentation within said single container that are required to perform a designated spinal stabilization procedure", as also recited in independent claim 3.

To the contrary, the Henniges reference discloses that the plate 10, the bone fasteners 12 and the driver tool 24 are individually packaged in separate containers, and are not integrally contained and sealed within a single container. Specifically, the plates 10 are contained in plate packaging (paragraphs 59 and 60), the fasteners 12 are contained in a separate container 76 (paragraph 79), and the driver 24 and other tools are contained in yet another separate instrument container (Figure 31). Indeed, there is no indication or suggestion whatsoever that each of these devices are integrally contained and sealed within a single container to maintain a sterilized condition prior to spinal surgery, as substantially recited in independent claim 3. Instead of providing a self-contained, all inclusive kit which packages the spinal components (including the spinal plate and bone screws) and the instrumentation within a single sterilized container to perform a designated spinal surgical procedure, the Henniges reference specifically teaches that the components and instruments are packaged separately from one another in individual containers, which is directly contrary to the inventive concept recited in independent claim 3.

Indeed, the Henniges reference discloses specific features for ensuring that the appropriate plate 10 and fasteners 12 are selected from product inventory for a particular surgical procedure. Specifically, the Henniges reference discloses that various plates 10 are color coded for identification purposes to ensure selection of the appropriate plate for the surgical procedure. ("The plates 10 can come in several different sizes and shapes depending on the specific application. By manufacturing the plates 10 with a unique color associated with each unique shape and size, confusion will be minimized and time will be saved.") (paragraph 59). Additionally, the Henniges reference discloses that "the package containing bioabsorbable plates 10 are marked with an identification mark, not shown. The mark allows the package with the plates 10 to be identified more precisely . . . in a manner that will allow the nurse or doctor to easily read and recognize the identification mark and the corresponding mark on the package containing the plate 10." Likewise, "color coding of the fasteners 12 will allow easy and quick identification of different fasteners 12" to ensure selection of the appropriate fasteners for the surgical procedure. (Paragraph 67).

Accordingly, the Henniges reference fails to disclose or suggest the concept of providing a self-contained kit which integrally contains the spinal components and instrumentation required to perform a designated spinal surgical procedure within a single container in a sterilized condition, as substantially recited in independent claim 3. Moreover, the Henniges reference seems to specifically teach away from this inventive concept, instead teaching that the plates 10 are contained within separate packages that are colored coded and individually marked to facilitate selection of an appropriate plate from product inventory, and that the fasteners 12 are likewise contained within separate packages that are colored coded and individually marked to facilitate selection of appropriate fasteners from product inventory.

The drawbacks and disadvantages associated with selecting surgical components and instruments from product inventory are specifically discussed in the background section of the subject application at page 1, line 18 to page 2, line 6. Specifically, the background section of the subject application sets forth the following:

> Many different types and sizes of implants, devices and instruments are available for treating various diseases, pathologies, injuries or malformations affecting the spine. In the past, the components required for a spinal surgical procedure have been supplied individually to surgical facilities, such as hospitals, trauma or ambulatory centers, medical or research laboratories, and surgical training facilities. Relatively high levels of inventory have been procured and maintained to accommodate the varying requirements associated with a spinal surgical procedure (e.g., anatomical requirements that dictate the selection of a particular size and configuration of implant, device and/or surgical instrument).
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> As should be appreciated, high inventory levels are expensive to procure and maintain, and are subject to loss, damage and possible theft. Moreover, the cost of even the most basic of surgical instrumentation can be quite high. Additionally, the availability of implants, devices and surgical instrumentation may be scarce, particularly with regard to remote or under-represented surgical facilities. Cleaning, sterilizing and maintaining surgical components can be both time consuming and expensive, particularly with regard to surgical instrumentation that is designed for repeated use. Additionally, cleaning and sterilization procedures may result in significant wait or down time in cases involving back-to-back scheduling of multiple surgical procedures.

The drawbacks and disadvantages discussed in the background section of the subject application are inherent in the individual packaging technique disclosed in the Henniges reference. However, the inventive concept recited in independent claim 3 addresses the

drawbacks and disadvantages of individually packaging components and instrumentation from product inventory by providing a self-contained kit including a spinal plate, bone screws and a screw driver instrument which are integrally contained and sealed within a single container to maintain a sterilized condition prior to the spinal surgery.

As set forth on page 3 of the Office Action, an assertion has been made that it would have been obvious to one of ordinary skill in the art to combine the kit disclosed in the Murphy reference, which includes components/instruments to perform a vertebroplasty procedure, with the devices disclosed in the Henniges reference to arrive at the invention recited in independent claim 3. Although the Murphy reference discloses devices and instruments used in association with a vertebroplasty procedure, there is no indication or suggestion regarding the inclusion of a spinal plate, bone screws and/or a driver instrument in the vertebroplasty kit. Indeed, as would occur to one of skill in the art, a vertebroplasty procedure is significantly different from a spinal stabilization procedure which utilizes a spinal plate and bone screws to attach the spinal plate to two or more vertebrae to stabilize/support a portion of the spinal column. Specifically, the vertebroplasty procedure disclosed in the Murphy reference is directed to a procedure for increasing the strength of vertebral bodies via injection of bone cement into an intervertebral cavity, whereas the surgical procedure recited in independent claim 3 involves the attachment of an elongate support plate to two or more vertebrae via bone screws to provide external stabilization and support to a portion of the spinal column. Although the Murphy references discloses a kit including components/instruments to perform a vertebroplasty procedure, there is no indication or suggestion regarding the inclusion of a spinal plate, bone screws and/or a driver instrument in the vertebroplasty kit. Additionally, one of skill in the art would not be motivated to add a spinal plate, bone screws and/or a driver instrument to the vertebroplasty kit.

For at least these reasons, the Applicant respectfully requests withdrawal of the rejection of independent claim 3 as being unpatentable over the Henniges reference in view of the Murphy reference. In summary, the Applicant has demonstrated that none of the asserted patent references disclose each of the elements and features recited in independent claim 3, and that is would not have been obvious to combine the Henniges reference with the Murphy reference to

arrive at the invention set forth in independent claim 3. Accordingly, the Applicant requests allowance of independent claim 3 and the claims depending therefrom.

Claims 5-9, 17, 20 and 22-26 depend from independent claim 3, and are submitted to be patentable for at least the reasons set forth above with regard to the patentability of independent claim 3. The Applicant notes that dependent claims 23-25 in view of the amendments to independent base claim 3. Also, dependent claim 17 has been amended to improve its form.

In addition to the reasons set forth above in support of the patentability of independent claim 3, further reasons support the patentability of claims 5-9, 17, 20 and 22-26 depending therefrom. For example, claim 5 recites that the surgical kit further comprises an interbody implant adapted for disposition within an intervertebral space between the first and second vertebrae. However, the Henniges reference, which is the only reference which discloses a spinal plate, bone screws and a driver tool, fails to disclose or suggest the inclusion of any type of interbody spinal implant. Additionally, although the Ray reference discloses an interbody implant, there is no teaching or suggestion whatsoever of regarding packaging of the interbody implant in a kit which includes a spinal plate, bone screws and a driver tool.

Additionally, claim 17 has been amended to recite that "said driver comprise a multi-piece instrument assembly including a first portion and a second portion, said first portion being selectively engagable with said second portion, one of said first and second portions including said end portion adapted to drivingly engage said bone screws into engagement with vertebral bone." As set forth on page 3 of the Office Action, claim 17 was rejected as being unpatentable over the Henniges reference in view of the Murphy reference. However, the Murphy reference clearly does not disclose any type of driver instrument including an end portion configured to drivingly engage bone screws into engagement with vertebral bone, much less a multi-piece driver instrument including a first portion that is selectively engagable with a second portion. Furthermore, although Henniges reference discloses a driver 24, the driver 24 likewise does not include a driver instrument comprising a multi-piece instrument assembly including a first portion that is selectively engagable with a second portion. To the contrary, the driver 24 comprises a single-piece driver instrument, including a handle that is permanently and non-removably attached to the driver shaft.

Furthermore, claim 26 recites that the surgical kit includes "a template including a number of images corresponding to one or more select sizes of said spinal plate member, one of said template images corresponding to a size of said spinal plate member included with the surgical kit." Dependent claim 26 was rejected based on the teachings set forth in the Banick reference. However, the element 64, which has been asserted to comprise a "template", is referred to in Banick as "instructions of use". One of ordinary skill in the art would understand that "instructions of use" is a writing or document that sets forth a method or technique for using a particular component, and does not comprise "a template including a number of images" that correspond to select sizes of a spinal plate member, and with "one of the template images corresponding to a size of the spinal plate member included with the surgical kit". Indeed, the Banick reference fails to disclose or suggest that the instructions of use 64 include any type of image that correspond to select sizes of a spinal implant, and with one of the template images specifically corresponding to the size of the spinal implant included with the surgical kit. Accordingly, the Applicant submits that none of the cited references disclose or suggest each of the elements and features recited in claim 26.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 3, 5-9, 17, 20 and 22-26.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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